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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,894	09/28/2001	Toru Takehisa	011307	1326

23850 7590 01/26/2005

ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP  
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 WASHINGTON, DC 20006

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/964,894	TAKEHISA ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/04 has been entered.

### ***Response to Arguments***

Applicant indicated that empirical evidence as to the unexpected superiority of the claimed range would be submitted. However, at this time no such evidence has been received and therefore the rejection stands.

Applicant's arguments filed January 22, 2004 have been fully considered but they are not persuasive. Applicant argues that the Anazawa reference teaches that composite membranes obtained by coating or clogging are undesirable. While it is noted in the reference that it's difficult to manufacture, it is not undesirable. The reference notes in column 2 that this material has an extremely high gas permeability rate and a higher gas exchange rate than the homogeneous membrane. These features are enormously useful in artificial lungs because the thickness can be correspondingly reduced. So there is motivation to look to compositions such as that taught by Kashiwabara and Motomura.

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Further, while it is true Motomura does not disclose the material claimed, it does teach that dimethyl ditetradecyl ammonium salt and dimethyl dioctadecyl ammonium salt are cationic compound having similar properties and produce similar results when dissolved with heparin (note claim 3 and the example on page 5.) This teaching would provide the motivation to modify Kashiwabara's material to make obvious the coating material recited in the claims. Finally, to use this material in Anazawa's device is considered obvious given the teachings provided for in that reference as discussed above.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology, i.e. comprise, comprises, and comprising. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al. (#5192320) in view of Kashiwabara et al. (EP-1057492) and Motomura et al. (EP-0769503).

Anazawa et al. disclose an artificial lung. The reference teaches (note column 6 lines 22-52) that the membrane of the device should be made of poly(4-methylpentene-1). The oxygen and ethanol permeation rates disclosed in the reference are within the limit defined in the claims. Not disclosed by this document is the surface coating that is derived from heparin and a quaternary aliphatic alkyl ammonium salt.

Kashiwabara et al disclose a blood compatible composition for use as a coating material in medical devices such as a pump-oxygenator, an artificial heart, etc. The essential material in the composition is an organic cationic compound and heparin or heparin derivative. The reference teaches (note paragraph 22) that in addition to an organic cationic compound having between 24-32 carbon atoms the compound can include an organic cationic compound having 4 alkyl groups and more than 32 carbon atoms. In Example 3, dimethyl didodecyl ammonium chloride and dimethyl ditetradecyl ammonium chloride were mixed in the proportions claimed. Thereafter heparin was

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dissolved in the mixture. The resulting product was a coating material having anti-thrombogenic properties.

Motomura et al. teach that dimethyl ditetradecyl ammonium salt and dimethyl dioctadecyl ammonium salt are cationic compounds having similar properties and produce similar results when dissolved with heparin (note claim 3 and the example on page 5).

Given these disclosures, it would have been obvious to one having ordinary skill in the art to add Kashiwabara et al's coating to the blood contacting side of the membrane in Anazawa et al's device for the purpose of imparting anti-thrombogenic properties thereto. To use dimethyl dioctadecyl ammonium salt in place of dimethyl ditetradecyl ammonium salt in Kashiwabara et al's product and process (noted above) would also have been obvious to one of ordinary skill in the art given Motomura et al's teaching that they are known equivalents for this purpose and would result in predictable variations in the lifetime of the coating, capability of the coating, etc.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

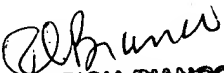
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 21<sup>st</sup>, 2005

Patricia M Bianco  
Primary Examiner  
Art Unit 3762

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**